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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,418	02/04/2004	Herve Le Mouellic	2356.0053-09	1932

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EXAMINER	
SHEN, WU CHENG WINSTON	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/770,418	LE MOUELLIC ET AL.	
	Examiner	Art Unit	
	Wu-Cheng Winston Shen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-104* is/are pending in the application.

4a) Of the above claim(s) *24-67 and 78-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application 10/770,418 filed on Feb. 04, 2004 is a CON of 10/639,754 08/13/2003 which is a CON of 08/466,699 06/06/1995 PAT 6,638,768, which is a CON of 08/301,037 09/06/1994 PAT 6,528,313, which is a CON of 08/048,056 04/19/1993 ABN, which is a CON of 07/598,679 12/19/1990 ABN. Relevant foreign applications are FRANCE PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989.

The preliminary amendments to the specification providing the abovementioned information, and remarks on the support individual claim in the specification filed on Feb. 04, 2004 are acknowledged.

Election/Restriction

1. Applicant's election with traverse of Group V, claims 68-77 in the reply filed on Nov. 3, 2006 is acknowledged. The traversal is on the ground(s) that, "the Examiner has not demonstrated that restriction is proper. "There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; and (B) There must be a serious burden on the examiner if restriction is required." M.P.E.P. § 803 (emphasis added). Thus, "If the search and examination of all the claims in an application can be made **without serious burden**, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions." M.P.E.P. § 803 (emphasis added). Applicants respectfully submit that the Examiner has not demonstrated

that examination of the full scope of the claims represents a serious burden and that, therefore, the restriction requirement is improper and should be withdrawn". This is not found persuasive because, as stated in Restriction Requirement and reiterated below.

Groups I-V are directed to a DNA construct directed to recited coding sequences in a particular arrangement. Groups I-V are patentably distinct one from each other because the DNA construct of Group I comprising sequences encoding a leader sequences and is fused in frame to a coding sequences encoding an expression product, particularly a transmembrane coding region of the MHC antigen; the DNA construct of Group II encodes no fusion protein before homologous recombination; the DNA construct of Group III encodes transcriptionally and translationally impaired positive selectable marker gene fused in frame to the transmembrane coding region of an integral membrane protein receptor for a cytokine that upregulates the expression of MHC antigen; the DNA construct of Group IV encodes no fusion protein either before or after homologous recombination; and the DNA construct of Group V encodes two distinct gene product, comprising a first DNA sequence and a second DNA sequence, wherein said first DNA sequence comprises a first coding sequence that encodes a first gene product that does not confer resistance to a selection agent involved in the selection of transformants.

Groups I-V are distinct from Group VI because Groups I-V are directed to a DNA construct for either inactivation or modification of a gene in a mammalian cell whereas Group VI is directed to a method for modifying a target DNA sequence in a mouse embryonic stem cell comprising recited steps. The structures of DNA constructs of Group I-V are not obvious over the steps and technical considerations of the method of Group VI.

In response to applicant's traversal, it is further emphasized that limitations of the compositions of the recited DNA constructs of Group I-V are patentably distinct, the search for claims in Group I-VI is distinct one from each other and not co-extensive and thereby presents search burdens on the examiner.

Upon further consideration, the requirement for further restriction on a receptor of claims 73-75, and the requirement for further restriction on a receptor of claims 42-44, 49-51, 56-58, 63-65, is withdrawn

The requirement is still deemed proper and is therefore made FINAL

Claims 24-67, 78-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. In the amended claims filed on November 6, 2006, applicant cancelled claims 10-15.

Status of claims: Claims 68-77 are currently under examination.

Priority date of claims

2. It is noted that the applicants filed in the Oath or Declaration claiming priority dates of foreign applications FRANCE PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989 in the instant application. The English translation of foreign applications FRANCE

PCT/FR90/00185 03/19/1990 and FRANCE 89 03630 03/20/1989 has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

To obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Therefore, the teachings of Kucherlapati et al. are applicable against the instant claims (See Claim Rejection - 35 USC § 102(e)).

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 68-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of phrase "wherein *the* expression product of said DNA construct comprises the second product that confers resistance to selection agent ---" in claim 68 fails to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it is not clear the recited term "*the* expression product of said DNA construct" refers to the first or the second gene product.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 68-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Song et al. (Song et al., Accurate modification of a chromosomal plasmid by homologous recombination in human cells. *Proc Natl Acad Sci U S A.* 1987 Oct; 84(19): 6820-4, 1987).

Song et al. teach the consequences of modifying mammalian cellular DNA sequences by homologous recombination. A plasmid carrying a 248-base-pair deletion in the neomycin phosphotransferase (neo) gene was introduced into hamster and human cells. The integrated, defective neo gene was used as a target for modification by a second round of transfection with a plasmid carrying a different (283-base-pair) deletion in the neo gene. Recombinants resulting in an intact neo gene were selected by their G418 resistance phenotype. The best ratio of homologous to nonhomologous recombination events was about 1:80. Analyses of the functional neo genes in various independent cell lines establish that simple crossovers (single and double) generated the wild-type neo genes. More specifically, Song et al. teach a plasmid bearing first

gene as bacterial guanine/xanthine phosphoribosyltransferase (gpt) gene and second gene as neomycin phosphotransferase (*neo*) gene (See Fig. 1, Song et al, and diagramed below).

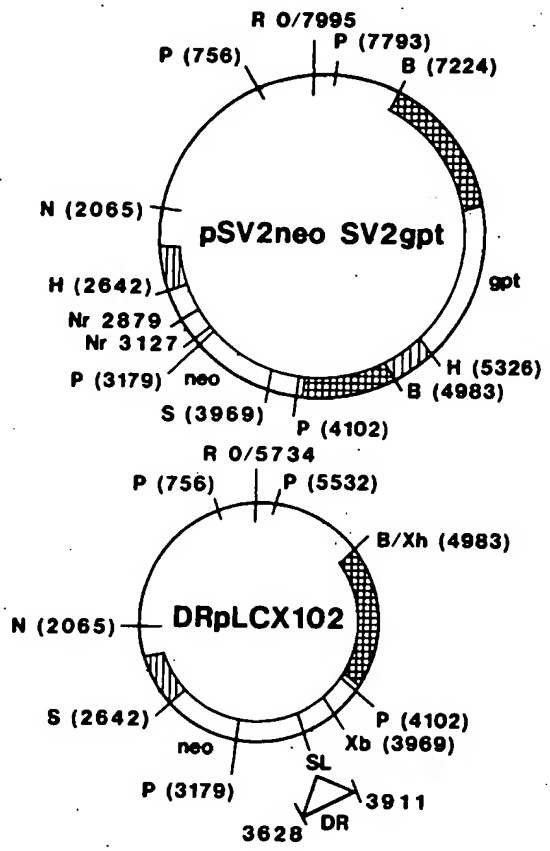

FIG. 1. Plasmids used for gene modification. (*Upper*) pSV2neo-SV2gpt. (*Lower*) pSV2neo-DR (DR-pLCX102). For each, key restriction enzyme recognition sites along with the nucleotide number are indicated. B, *Bam*HI; H, *Hin*dIII; N, *Nde* I; Nr, *Nar* I; P, *Pst* I; S, *Sma* I; SL, *Sal* I; Xb, *Xba* I; Xh, *Xho* I. Thin lines represent pBR322 sequences. Open boxes, *neo* or *gpt* sequences. Cross-hatched boxes, simian virus 40 origin and early promoter sequences. Hatched boxes, simian virus 40 splicing and polyadenylylation signals.

5. Claims 68-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Kucherlapati et al. (U.S. Patent No. 6,514,752, Date of Patent, Feb. 4, 20043, U.S. Application No 08/443,613,

which is a divisional of application Ser. No. 08/175,469, filed Dec. 30, 1993, now U.S. Pat. No. 5,574,205, which is a continuation-in-part of application Ser. No. 07/990,879, filed Dec. 11, 1992, now U.S. Pat. No. 5,413,923, which was a continuation-in-part of application Ser. No. 07/611,020 filed Nov. 9, 1990, now U.S. Pat. No. 5,416,260, which was a continuation-in-part of application Ser. No. 07/431,872 filed Nov. 6, 1989, now abandoned, and application Ser. No. 07/385,651, filed Jul. 25, 1989, now abandoned, and claims priority to PCT/US90/04178, filed Jul. 25, 1990, the disclosures of which are all incorporated by reference therein).

Kucherlapati et al. teach homologous recombination for universal donor cells and chimeric mammalian hosts and that homologous recombination being employed to inactivate genes, particularly genes associated with MHC antigens. Particularly, the β_2 -microglobulin gene is inactivated for reducing or eliminating the expression of functional Class I MHC antigens. The resulting cells may be used as universal donor cells. In addition, embryonic stem cells may be modified by homologous recombination for use in producing chimeric or transgenic mammalian hosts, which may be used as source of universal donor organs, or as models for drug and transplantation therapies. Methods for homologous recombination in non-transformed mammalian somatic cells are also described (See, title and abstract).

With regard to a DNA construct (claim 68-77 of instant application), Kucherlapati et al. teach the followings:

(i) A DNA gene inactivation construct for homologous recombination in the genome of a mammalian cell, comprising at least 100 bp of a sequence homologous with a gene locus of a subunit of an MHC antigen flanking a sequence encoding a selectable marker gene capable of expression in a mammalian cell, wherein the sequence encoding a selectable market gene is

downstream from a sequence encoding a leader sequence and is fused in frame to a transmembrane coding region of the subunit of the MHC antigen, wherein upon homologous recombination, said gene locus is inactivated, and wherein, as a result of homologous recombination, at least one functional MHC antigen is not expressed (claim 1);

(ii) A DNA construct, comprising DNA encoding in the 5' to 3' direction, a region of homology to a target gene, a foreign promoter/enhancer joined to a gene sequence having a first epitope that binds to a ligand for detection, a selectable marker gene, and a second region of homology to said target gene, said target gene encoding a gene product having a second epitope, and said target gene being selected from the group consisting of a gene encoding a subunit of an MHC antigen and a gene encoding a protein that upregulates expression of MHC antigens, wherein, upon homologous recombination of said DNA construct into a genome, a recombinant, secreted fusion protein comprising said first epitope that binds to a ligand for detection and said second epitope is expressed in targeted cells, and wherein, as a result of homologous recombination, at least one functional MHC antigen or protein associated with expression of MHC antigens is not expressed (claim 6);

(iii) A DNA construct comprising DNA encoding a transcriptionally and translationally impaired positive selectable marker gene fused in frame to the transmembrane coding region of an integral membrane protein receptor for a cytokine that upregulates the expression of MHC antigen; wherein the expression product of said DNA is a fusion protein comprising a functional selectable marker expressed on the cytoplasmic side of said membrane (claim 8); and

(iv) A DNA construct comprising DNA encoding a transcriptionally and tanslationally impaired positive selectable marker gene fed downstream and in frame to the transmembrane

coding region of an integral membrane protein that upregulates MHC antigen expression, wherein the expression product of said DNA construct is a fusion protein comprising a functional, selectable marker (claim 13).

With regard to the limitation selective agent is neomycin (claim 69 of instant application), Kucherlapati et al. teach for an inserted gene, of particular interest is a gene, which provides a marker, e.g., antibiotic resistance such as neomycin resistance, including G418 resistance (See column 9, second paragraph).

With regard to the limitations (i) the expression product of said DNA construct localizes in the cytoplasm (claim 70 of instant application), and (ii) the first gene product is part or all of an interferon (claim 77 of instant application), Kucherlapati et al. teach the genes which are introduced may also serve for protein production, where the proteins may be retained intracellularly or be secreted. Production of proteins may include growth factors such as, e.g., G-, M-, and GM-CSF, epidermal growth factor, platelet derived growth factor, transforming growth factor, etc; lymphokines, such as the interleukins; hormones, such as ACTH, somatomedin, insulin, angiotensin, etc.; coagulation factors, such as Factor VIIIC normal versions of the proteins associated with genetic diseases such as adenosine deaminase or the protein associated with cystic fibrosis; protective agents, such as 1-antitrypsin; regulatory proteins or enzymes associated with the production of amino acid free products, such as the expression of tyrosine hydroxylase for the production of L-dopamine, and the like. The genes may be under the transcriptional control of a constitutive, promoter or inducible promoter (including enhancer sequence). In the latter situation, regulation may result by induction by a

naturally occurring signal or as a result of introduction into the host of an exogenous signal (column 13, second paragraph).

With regard to the limitation a receptor (claims 71-75 of instant application), Kucherlapati et al. teach any integral membrane protein may be targeted, including cluster of differentiation "CD" antigens. Of particular interest are MHC antigens, T cell receptors and subunits, e.g. α, β, η, ζ and various receptor proteins including interferon receptors, neurotransmitter receptors, growth factor receptors, colony stimulating factor receptors, etc (See column 12, second paragraph). It is noted that (i) growth factor receptors encompass retinoic acid receptor (claim 73 of instant application), (ii) neurotransmitter receptors encompass β3 adrenergic receptor (claim 74 of instant application), and (iii) differentiation "CD" antigens encompass CD4 cell surface antigen, which is an HIV receptor (claim 75 of instant application).

With regard to the limitation the first gene product is part or all of an interferon (claim 76 of instant application), Kucherlapati et al. teach interferon-gamma (IFN-gamma) is a cytokine that is produced during the process of infection and inflammation which exhibits potential antiviral, anti-proliferative and immunomodulatory effects (column 3, last paragraph).

Obviousness-type double patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 68-77 of instant application No. 10/770,418 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90, 99 and 108 of the other U.S. application of copending application No. 10/639,754. The instant application No. 10/770,418 is a continuation of the copending application No. 10/639,754.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 68-77 of instant application No. 11/115,868 are drawn to a DNA construct, encoding two distinct gene products, comprising a first DNA sequence and a second DNA sequence, wherein said first DNA sequence comprises a first coding sequence that encodes a first gene product that does not confer resistance to a selection agent involved in the selection of transformants, and said second DNA sequence comprises a second coding sequence that encodes a second gene product that confers resistance to a selection agent involved in the selection of transformants, wherein the second DNA sequence is downstream of the first DNA sequence, wherein the expression product of said DNA construct comprises the second product that confers resistance to a selection agent involved in the selection of transformants, in functional form, whereas claims 90, 99 and 108 of the other copending U.S. application No. 10/639,754 are drawn to the followings:

(i) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of a recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the recipient gene; wherein the heterologous DNA sequence is between the first DNA sequence of the recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a first coding sequence that encodes a first product that is not a marker involved in the selection of cells transformed with said nucleic acid molecule; and wherein the second insertion DNA sequence comprises a second coding sequence that encodes a second

product that is a marker involved in the selection of cells transformed with said nucleic acid molecule, and a promoter allowing the expression of the second product in a cell transformed with said nucleic acid molecule (claim 90);

(ii) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of the recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the endogenous recipient gene; wherein the heterologous DNA sequence is between the first DNA sequence of the recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a first coding sequence that encodes a first product that is not a marker involved in the selection of cells transformed with said nucleic acid molecule, and a regulatory sequence for regulating the expression of the first product; and wherein the second insertion DNA sequence comprises a second coding sequence that encodes a second product that is a marker involved in the selection of cells transformed with said nucleic acid molecule, and a promoter allowing the expression of the second product in a cell transformed with said nucleic acid molecule (claim 99); and

(iii) A nucleic acid molecule comprising a recombinant recipient gene, wherein the recombinant recipient gene comprises: (A) a first DNA sequence of the recipient gene; (B) a second DNA sequence of the recipient gene, downstream of the first DNA sequence of the recipient gene; and (C) a DNA sequence heterologous with respect to the endogenous recipient gene; wherein the heterologous DNA sequence is between the first DNA sequence of the

recipient gene and the second DNA sequence of the recipient gene; wherein the heterologous DNA sequence comprises a first insertion DNA sequence and a second insertion DNA sequence; wherein the first insertion DNA sequence comprises a regulatory sequence; and wherein the second insertion DNA sequence comprises a coding sequence that encodes a product that is a marker involved in the selection of cells transformed with said nucleic acid molecule, and a promoter allowing the expression of the product in a cell transformed with said nucleic acid molecule (claim 108).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

6. No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Wu-Cheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-273-3157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30

PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent examiner, Peter Paras, can be reached on (571) 272-4517. The fax number for TC 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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